Lenalidomide

Adverse Event Report Form

(Adverse Event Report Form related to Lenalidomide EU RMP version 2.2)

Reporter's details		
Title: (Mr, Mrs, Miss, Dr, etc)	First Name(s):	Surname:
Job Title:		
Address:		
City, Town:	Country:	
Post code:	Country:	
Phone Number:	Fax Number:	
Email address:		

Patient information		
Patient ID (initials):	Age:	Date of birth: DD MM YYYY
Weight (Kg):		Height (cm):

Adverse event		
Overall diagnosis of the event	Event onset date:	DD MM YYYY
	Event stop date:	DD MM YYYY
	Or ongoing at time of reporting (if less than 24 hours)	HR MIN

Description of adverse event	**Outcome of adverse event**	
Symptoms and treatment	Recovered	TICK ☐
	Recovered with sequele	TICK ☐
	Not recovered	TICK ☐
	Unknown	TICK ☐
	Death	TICK ☐
	Date of death	DD MM YYYY
	Possible cause of death	

If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event.

Seriousness of adverse event (tick all that apply)	
Death	TIC ☐
Life-threatening	TIC ☐
Hospitalization or prolonged hospitalization	TIC ☐

Company

Address

City, Town

Country

Persistent or significant disability or incapacity	TIC ☐
Congenital anomaly/birth defect	TIC ☐
Other medically important condition or event	TIC ☐
Non-serious	TIC ☐

Tel:
Fax:
Email:

Medical history (May be supplied as a copy of Medical file if up to date)		
Current or past relevant medical history (including concurrent illness, allergy, smoking, alcohol abuse)	YES ☐	NO ☐
If YES please specify		

Suspect drug						
Drug, Dosage-form, Strength, Route (e.g. Tab 5mg, oral)	Dose & frequency	Batch no.	Therapy Start date	Therapy Stop date	Causal relationship 1= Not related 2 = Related	Indication for use of drug
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		

Other medication (Medication taken during the past 3 months prior to the event - May be supplied as a copy of Medical file if up to date)						
Drug, Dosage-form, Strength, Route (e.g. Tab 5mg, oral)	Dose & frequency	Batch no.	Therapy Start date	Therapy Stop date	Causal relationship 1= Not related 2 = Related	Indication for use of drug
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		

Action taken, suspect drug							
Continued unchanged	☐	Continued, dose or dose regimen changed	☐	Withdrawn	☐	N/A	☐
Please specify if dose or dose regimen changed:							

Notification					
Initial report	☐	Final report	☐	Follow-up report	☐
Name:					
Title:					

Signature:

Data Privacy statement:

All personal information will be strictly confidential and not used for any other purposes than preparing a report form.